REMARKS/ARGUMENTS

Claims 1-16 are currently pending in the above-identified application. The Specification has been amended to address matter that was incorporated by reference, and a brief description of the drawings has been inserted. Claims 3-5 and 8-14 have been amended. No new matter has been added by these amendments. Certain claims have been amended for purposes of clarity and to better comply with accepted U.S. practice.

Objection to the Specification

Per the request of the Examiner, Applicants have added a "Brief Description of Drawings". No new matter has been added.

The Examiner has also objected to the specification based on an allegedly improper incorporation by reference of WO94/14069. Applicants respectfully point out that the material incorporated by reference includes "starting material" and crude mycobacterial mass" which are described in said WO94/14069, and not to the preparation designated KP90. For purposes of consistency with the parent application, and without acquiescing to the objection, the present specification has been amended to incorporate the same material that was incorporated into the parent application. The objection is thus obviated.

Claim Rejections - 35 U.S.C. § 112

Claims 1-16 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Office states that it is unclear how one detects a whole Mycobacterium by merely detecting Ag-Ab complexes, and how adding both the antigen and antibody to a sample detects whole Mycobacterium which may or may not be present.

The present claims do not require that a whole Mycobacterium organism per se be detected, only the such an organism (or antibody thereto) be identified by means of

antigen/antibody complexes, whether they be formed via antigenic components or even whole organism or the like. The claims clearly state that detection of complexes formed from the one or more cross-reacting antibodies and the one or more cross-reacting antigens permit the identification of the Mycobacterium species.

Similarly, nowhere is there a claim to detecting a whole Mycobacterium which may or may not be present by adding both the antigen and the antibody to a sample. The method for detecting the immune complexes permits the identification of the Mycobacterium that is or was present in the individual being tested.

In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-16 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for M. tuberculosis KP90 antigen preparation and antibodies produced against M. *tuberculosis*, does not reasonably provide enablement for other species of Mycobacteria.

Applicants point to the general utility of the claims method for identifying and monitoring a Mycobacterial species responsible for infection of an individual. The claims are not directed to a particular set or group of Mycobacterial species or their particular immuno-cross-reactive antigens (ImCRACs) that are characteristic of a Mycobacterial species. These aspects are set forth in the published patent application, WO A 94/14069, which has been incorporated by reference into the present Specification. Indeed, issued U.S. Patent 5,817,473 is based on the disclosure of said WO A 94/14069. This patent discloses, *inter alia*, the use of ImCRACs for the detection of sera from individuals having infections due to species of Mycobacteria. The present method is not limited to any one Mycobacterial species and can be used, consistent with the ImCRAC technology, to identify and monitor infections due to a range of Mycobacterial species. Therefore, the present claims are enabled by the Specification, and Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

Double Patenting

Claims 1-16 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 6,733,983. Although the conflicting claims are not identical, the Office alleges they are not patentably distinct from each other because both sets of claims are drawn to methods of identifying Mycobacterium utilizing the same methods steps and reagents.

To further expedite prosecution of the present application, Applicants are obtaining from the owner of the present application and said US 6,733,983 a terminal disclaimer that disclaims the terminal part of the statutory term of any patent granted on the present application, which would extend beyond the expiration date of the full statutory term of prior U.S. Patent No. 6,733,983. The terminal disclaimer will be submitted shortly under separate cover.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Dated: January 7, 2005

By: Steven W. Parmelee
Steven W. Parmelee
Reg. No. 31,990

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 206-467-9600
Fax: 415-576-0300
SWP:dmz
60394455 v1